

UNITED STATES PATENT AND TRADEMARK OFFICE

ENITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.usplo.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/909,843	07/23/2001	Daniel C. Carter	P07087US00/BAS	8801
881	7590 05/27/2004	EXAMINER		INER
STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET			SONG, MATTHEW J	
SUITE 900 ALEXANDRIA, VA 22314			ART UNIT	PAPER NUMBER
			1765	······································

DATE MAILED: 05/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)	F
	09/909,843	CARTER, DANIEL	_ C.
Office Action Summary	Examiner	Art Unit	
	Matthew J Song	1765	
The MAILING DATE of this communication app Period for Reply	ears on the cover s	heet with the correspondence ad	dress
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however within the statutory minimality ill apply and will expire SI. cause the application to be	er, may a reply be timely filed rum of thirty (30) days will be considered timel K (6) MONTHS from the mailing date of this or ecome ABANDONED (35 U.S.C. § 133).	
Status			
1) Responsive to communication(s) filed on 15 M. 2a) This action is FINAL . 2b) This 3) Since this application is in condition for allowar closed in accordance with the practice under E.	action is non-final	al matters, prosecution as to the	e merits is
Disposition of Claims			
4) ☐ Claim(s) 1 and 5-10 is/are pending in the application 4a) Of the above claim(s) is/are withdraw 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1 and 5-10 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or	vn from considerat		
Application Papers			
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Examine	epted or b) objed drawing(s) be held ir ion is required if the	abeyance. See 37 CFR 1.85(a). drawing(s) is objected to. See 37 CF	` '
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priority application from the International Bureau * See the attached detailed Office action for a list	s have been receiv s have been receiv ity documents hav ı (PCT Rule 17.2(a	red. red in Application No e been received in this National i)).	Stage
Attachmont(c)			
Attachment(s) 1) Notice of References Cited (PTO-892)	4) 🔲 Ir	terview Summary (PTO-413)	
Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	5)	aper No(s)/Mail Date otice of Informal Patent Application (PTC ther:)-152)
J.S. Patent and Trademark Office PTOL-326 (Rev. 1-04) Office Ac	tion Summary	Part of Paper No./Mail	Date 040521

Art Unit: 1765

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/14/2004 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites, "said tray having an upper surface formed so as to be substantially coplanar with the place of the upper openings of said plurality of sealable wells and the coverslip when place on said openings" in line 5-7. The instant specification merely teaches an upper surface 16 coplanar

with an opening 28 in the sealable well. There is no support in the instant specification for an upper surface, which is coplanar with a coverslip.

- 4. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites, "maintaining sufficient separation between the lower surface of the first tray and the upper surface of the second stackable tray" in line 15-16. There is no support in the instant specification for "sufficient".
- 5. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites, "to allow protein crystallization to take place in the second tray without disruption to the coverslip" in line 19-20. The instant specification merely teaches tray can carry out protein crystal growth processes or cell culturing processes without the need for an extra plastic lid to protect the wells and the biological or chemical processes occurring therein from harm or disruption by a tray stacked on top of it, note page 7. There is no support for "without disruption to the coverslip".

Application/Control Number: 09/909,843 Page 4

Art Unit: 1765

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites, "maintaining sufficient separation between the lower surface of the first tray and the upper surface of the second stackable tray" in line 15-16. It is unclear what "sufficient separation" encompasses. There is no numerical value defined to describe what a "sufficient separation" is. In other words, the separation can be 1 mm or 1 angstrom because there is no definition of what is "sufficient".

Claim Rejections - 35 USC § 103

- 8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 9. Claims 1 and 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carter (US 5,419,278) in view of Miller (US 5,384,103) or Tabler (US 4,600,103).

Carter discloses an apparatus for using in carrying out a chemical or biological process, note entire reference, comprising a stackable tray 12 containing at least one sealable well 14 in which a protein crystallization is performed, where the tray has an upper surface substantially

Art Unit: 1765

30 when placed on said openings (Fig 1 and Fig 3a). Carter also discloses the tray is constructed of a transparent moldable plastic material or glass and clear plastic tape is used to seal the tray (col 6, ln 1-67). Carter also discloses a hanging drop protein crystallization (col 1, ln 55-67) and a protein solution (col 8, ln 1-67). Carter also discloses ledges for coverslips, this reads on applicant's sealable with a coverslip (col 7, ln 20-30).

Carter does not discloses the side walls surrounding the plurality of wells having a lowermost portion which extends beyond the lower surface of the tray comprising the place of the lowermost portions of the sealable wells and having a lower end configuration so as to allow the tray to be stacked on the outer portion of the upper surface of a second stackable tray positioned below the first tray while maintaining sufficient separation between the lower surface of the first tray and the upper surface of the second stackable tray below the first one so as to allow stacking of the trays without the lower surface of the first tray impinging upon the coverslips at the upper openings of the sealable wells of the second tray stacked below the first tray and to allow protein crystallization to take place in the second tray without disruption to the coverslips.

In an apparatus for stacking trays, note entire reference, Miller teaches feet 82, 84, 86, this reads on applicant's extended sidewalls beyond the lowermost surface of the sealable well, of a tray 12 are contoured to securely engage the sides of a tray placed beneath then at their corners and the feet permit trays to be interlocked when they are stacked, whether covers are used or not (col 2, ln 30-67 and Fig 1). Miller also teaches the larger stepped regions abut the upper edges of the tray's walls and engage them when one tray is set up on top of another tray

Art Unit: 1765

(col 5, ln 1-15), this reads on applicant's sufficient separation because the stepped region provides separation between the two trays which can be used with a cover. It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Carter with Miller because stacked trays are stacked more securely and are able to withstand below without the contents of the tray becoming dislodged, whether or not a cover is used (col 8, ln 1-35).

Referring to claim 6, the combination of Carter and Miller teaches all of the limitations of claim 6, as discussed previously, except the apparatus further comprises an automated system for stacking and unstacking the stackable trays.

It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Carter and Miller by adding an automated system for stacking and unstacking the stackable trays to reduce manufacturing time and possible contamination. Also automating a manual activity is obvious (MPEP 2144.04).

Referring to claim 7, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. The apparatus taught by the combination of Carter and Miller has all of the structural features, as applicant, and would be capable of the intended use claimed by applicant.

Tabler teaches a stackable tray apparatus comprising a tray stacked in two or more levels adapted to be handled by automated equipment and the tray comprises high side walls which extend below the midplane at the outer edge so that one tray may be stacked on a like tray in a interlocking arrangement (Fig 9-11), this reads on applicant's extended sidewall beyond the lower most surface of the sealable well, note entire reference. The extended sidewalls maintain a

Art Unit: 1765

sufficient separation between the lower surface of the first tray and upper surface of the second tray without the lower surface impinging on the openings of the second tray, which would allow a process to occur without disruption (Fig 10). It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Carter with Tabler because the interlocking portions of the tray prevent the trays from shifting, thereby increasing the stability of a stacked arrangement.

Referring to claims 3-4 and 7, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. The apparatus taught by the combination of Carter and Tabler has all of the structural features, as applicant, and would be capable of the intended use claimed by applicant.

Referring to claim 6, the combination of Carter and Tabler teaches automated equipment used to handle trays ('103 col 2).

Response to Arguments

10. Applicant's arguments filed 1/14/2004 have been fully considered but they are not persuasive.

In response to applicant's argument that it was not obvious to develop a method of achieving separation between the trays to allow sufficient spacing to avoid disruption of a coverslip, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The combination of Carter and Miller and the combination of Carter and Tabler

Art Unit: 1765

teaches using sidewalls, which extend below the lower surface to increase stability of the stacked trays.

Applicant's argument that no one else in the relevant art suggests the improvement is noted but is not found persuasive. Applicant's invention pertains to an apparatus is not limited to the field of protein crystallization, as suggested by applicants. Applicant's invention is related to stackable trays and the means used to stack the trays, the extended sidewalls of the tray, was disclosed by Miller and Tabler. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Carter with Tabler or Miller's stacking means to improve the stability of the stacked trays.

In response to applicant's argument that Miller and Tabler is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Miller and Tabler are reasonably pertinent to the problem with which the applicant is concerned, which is an improvement in stacking trays, which Miller and Tabler are related. Miller teaches stacking trays with or without lids, which is the problem with which the applicant was concerned.

In response to applicant's argument that the prior art does not recognize or attempt to solve the problem overcome by Applicant's invention, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The combination of Carter and

Art Unit: 1765

Miller and the combination of Carter and Tabler teaches using sidewalls, which extend below the lower surface to increase stability of the stacked trays.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Miller teaches stacking the trays whether or not a cover is used, as suggested by applicant. However, Carter is relied upon as a teaching of using a coverslip, note Figs 3a and 3b. Miller is merely open to having a tray with a cover, such as the apparatus taught by Carter.

Applicant's argument that Miller teaches away from the claimed invention is noted but is not found persuasive. Miller teaches stacking the trays whether or not a cover is used, as suggested by applicant. Miller merely teaches an alterative embodiment in which a cover is not used. Miller does teach using a cover; therefore does not teach away from the claimed invention. Furthermore, Miller is not relied upon as a teaching of using a cover, Carter teaches this limitation.

Applicant's argument that Tabler does not teach a tray used in protein crystallization is noted but is not found persuasive. Tabler teaches a means for stacking trays in general and is not limited to bakery trays, as suggested by applicant. Furthermore, Carter teaches the protein crystallization tray limitation with sealable wells and Tabler is not relied upon to teach this feature.

In response to applicant's argument that Tabler and Miller teach trays not related to protein crystallization, a recitation of the intended use of the claimed invention must result in a

structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 USPO 235 (CCPA 1967) and In re Otto, 136 USPO 458, 459 (CCPA 1963). The structure taught by the combination of Carter and Miller or the combination of Carter and Tabler teaches a protein crystallization tray with extended sidewalls used for stacking trays, as applicant.

Applicant's argument that Miller does not teach sufficient separation between the trays has been considered but has not been found persuasive. Miller teaches each foot member 90, 92, 94, and 96 includes at least two cylindrical stepped regions 98 and 100 and the stepped region 100 abut the upper edges of the tray's walls (col 4, ln 64 to col 5, ln 11 and Fig 1). Therefore, the stepped region 100, which abuts the tray's walls, will provide sufficient separation between two stacked trays because the coverslip taught by Carter is below the top surface of the tray (Figs 3a-3b); therefore any separation between the tray will provide sufficient separation such that the lower surface does not impinge on the upon the coverslips.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

McCorkle, Jr. et al (US 5,906,165) teaches an apparatus for securely stacking trays with an extension of the side 8.

Breen (US 5,054,629) teaches an adjustable means 2 for stacking trays.

McPherson et al (US 5,096,676) discloses an apparatus for protein crystallization, comprising a stackable tray containing at least one sealable well **20** having a substantially coplanar surface with an upper opening in the sealable well and a flange portion of the side wall, where the side walls having a lower end configuration so as to form an outer base (Figs 1-6 and col 3-6). McPherson et al also discloses a thin plastic material having an adhesive on the lower surface to seal the wells **20**, the tray is made of a plastic and the well **20** is filled with a protein solution (col 4, ln 1-67).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Song whose telephone number is 571-272-1468. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nadine Norton can be reached on 571-272-1465. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew J Song

Examiner Art Unit 1765

MJS

NADINE G. NORTON SUPERVISORY PATENT EXAMINER